



K954354

GE Medical Systems

General Electric Company  
P.O. Box 414, Milwaukee, WI 53201

APR 12 1996

0.2T GP Neck/Shoulder Coil

September 14, 1995

General Electric Medical Systems

**SUMMARY OF INFORMATION REGARDING SAFETY AND EFFECTIVENESS**

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

Contact: Larry A. Kroger  
Phone: 414-544-3894  
Fax: 414-544-3863

Product: 0.2T GP Neck/Shoulder Coil  
Manufactured by GE Yokogawa Medical System, Ltd.  
Tokyo, Japan

1) **Indications for Use**

The 0.2T GP Neck/Shoulder Coil expands the capability of the 0.2T MR imaging system. It accommodates and improves imaging of the cervical spine, neck, shoulder and surrounding structures.

2) **Device Description**

The 0.2T GP Neck/Shoulder Coil is a receive-only, linear, circular solenoidal coil contained in a biocompatible outer shell. The coil comes with an adjustable positioning base and comfort pads for support.

3) **Marketing History**

The 0.2T GP Neck/Shoulder Coil has not been previously marketed by GE Medical Systems.

4) **Potential Adverse Effects on Health**

The use of the 0.2T GP Neck/Shoulder Coil does not result in any additional potential hazards compared to previously marketed receive-only surface coils.

5) **Conclusions**

It is the opinion of GE Medical Systems that the 0.2T GP Neck/Shoulder Coil is substantially equivalent to the presently marketed GE Shoulder Surface Coil (#K892235).